

Complaint alleges the following facts, which the Court accepts as true for the sole purpose of deciding the instant motion. In 1999, Plaintiff Barbara McPhee (“Plaintiff-wife”) underwent a hip replacement at Altoona Hospital, Blair County, Pennsylvania. (*See* Doc. 35 at ¶ 10). During the hip replacement procedure, a combination of medical devices² was surgically implanted into the Plaintiff-wife’s hip. (*See* Doc. 35 at ¶ 5; Doc. 36 at ¶ 10). The specific components of the implanted device include: a Duraloc Sector Cup, 1245-80-056, R4RDV1016, Enduron Polyethylene 124-50-025, SS71CJ1051, AML Hip System MMA 1557-02-000, RWBET1010, Depuy Articul/EZE Ball 1365-11-00, S1LBE1014 (collectively referred to as “implant” or “device”). (*See* Doc. 35 at ¶ 5; Doc. 36 at ¶ 10).

Defendant, DePuy Orthopedics, Inc., manufactured the implanted device. (Doc. 35 at ¶¶ 4-5). The components of the implanted device are subject to regulation by the U.S. Food and Drug Administration (“FDA”) pursuant to the Medical Device Amendments (“MDA”) to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360 *et seq.*, and 21 C.F.R. § 803 *et seq.* (Doc. 35 at ¶¶ 6-7). The FDA approved the sale of the device components based on Defendant’s applications for Pre-Market Approval (“PMA”). (Doc. 35 at ¶¶ 7-8).

In November 2008, Plaintiff-wife experienced pain while walking in her home. (Doc. 35 at ¶ 11). Immediately thereafter, Plaintiff-wife visited a physician, Robert Singh, M.D., who informed her that the shaft of the implant had shattered. (Doc. 35 at ¶ 12). Plaintiff-wife underwent surgery on or about June 15, 2009, to remove the broken implant and replace it with a

² It is unclear from the Second Amended Complaint whether the implanted devices consist of one or several devices. (*See* Doc. 35 at ¶¶ 5-6). The Complaint refers to the device as “the implant or combination of devices involved” (Doc. 35 at ¶ 5), and consistently refers to the materials in the singular as “implant” or “device.” Defendant refers to the implanted materials in the aggregate as “components” and “medical devices.” (*See, e.g.*, Doc. 37 at 2). Whether the implanted materials are a single device, multiple devices, or a combination of devices, is immaterial to the resolution of the instant motion. Accordingly, consistent with the Plaintiffs’ Second Amended Complaint, the Court will refer to the implanted materials in the singular as “device” or “implant.”

new device. (Doc. 35 at ¶ 14). Since the surgery, Plaintiff-wife has suffered progressively worsening severe and debilitating pain. (Doc. 35 at ¶ 15).

Plaintiffs commenced the instant action in the Court of Common Pleas of Blair County, Pennsylvania to recover damages from Defendants DePuy, DePuy Orthopedics, Inc., and Johnson & Johnson. (*See* Doc. 1). Defendants removed the case to this Court on December 19, 2011. (Doc. 1).

On January 23, 2012, Defendants filed a Motion to Dismiss (Doc. 11) the Plaintiffs' Complaint, which the Plaintiffs opposed (Doc. 15). On February 23, 2012, in accordance with a stipulation of the parties, the Court dismissed Defendants DePuy and Johnson & Johnson with prejudice (Doc. 22), leaving DePuy Orthopedics, Inc., as the sole remaining Defendant. Thereafter, on September 28, 2012, the Court granted Defendant's first motion to dismiss but provided Plaintiffs with 21 days leave to amend Counts I, V, and VI. (Doc. 33).

Plaintiffs filed an Amended Complaint (Doc. 34) on October 31, 2012, and a Second Amended Complaint (Doc. 35) on November 5, 2012. On November 20, 2012, Defendant filed the instant Motion to Dismiss (Doc. 36) and a brief in support (Doc. 37). On December 28, 2012, Plaintiffs filed a Brief in Opposition to Motion to Dismiss (Doc. 40) and a Response to Motion (Doc. 41). With leave from the Court, Defendant filed a Reply Brief (Doc. 44) on January 16, 2013.

Plaintiffs' Second Amended Complaint contains two counts against Defendant DePuy Orthopedics, Inc. (*See* Doc. 35).³ In Count I, Plaintiffs assert a negligence claim against Defendant. (Doc. 35 at ¶¶ 18-19). In Count II, Plaintiffs assert a loss of consortium claim

³ Plaintiffs have abandoned their express warranty claim. (*See* Doc. 40 at 2).

against Defendant. (Doc. 35 at ¶¶ 20-24). Defendant now moves for the dismissal of both Counts of Plaintiffs' Second Amended Complaint for failure to state a claim.

IV. STANDARD OF REVIEW

Defendant moves to dismiss the Plaintiffs' claims in the Second Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The Federal Rules of Civil Procedure require that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Federal Rule of Civil Procedure 12(b)(6) allows a party to seek dismissal of a complaint or portion of a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Although the federal pleading standard has been "in the forefront of jurisprudence in recent years," *Fowler v. UPMC Shadyside*, 548 F.3d 203, 209 (3d Cir. 2009), the standard of review for a Rule 12(b)(6) challenge is now well established.

In determining the sufficiency of a complaint, a district court must conduct a two-part analysis. First, the court must separate the factual matters averred from the legal conclusions asserted. *See Fowler*, 548 F.3d at 210. Second, the court must determine whether the factual matters averred are sufficient to show that the plaintiff has a "plausible claim for relief." *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). The complaint need not include "detailed factual allegations." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Moreover, the court must construe the alleged facts, and draw all inferences gleaned therefrom, in the light most favorable to the non-moving party. *See id.* at 228 (citing *Worldcom, Inc. v. Graphnet, Inc.*, 343 F.3d 651, 653 (3d Cir. 2003)). However, "legal conclusions" and "[t]hreadbare recitals of the elements of

a cause of action . . . do not suffice.” *Iqbal*, 556 U.S. at 678. Rather, the complaint must present sufficient “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 263 n.27 (3d Cir. 2010) (quoting *Iqbal*, 556 U.S. at 678).

Ultimately, whether a plaintiff has shown a “plausible claim for relief” is a “context specific” inquiry that requires the district court to “draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 679. The relevant record under consideration includes the complaint and any “document integral or explicitly relied on in the complaint.” *U.S. Express Lines, Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)). If a complaint is vulnerable to dismissal pursuant to Rule 12(b)(6), the district court must permit a curative amendment, irrespective of whether a plaintiff seeks leave to amend, unless such amendment would be inequitable or futile. *Phillips*, 515 F.3d at 236; *see also Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000) (“[L]eave to amend generally must be granted unless the amendment would not cure the deficiency.”).

V. DISCUSSION

Defendant moves to dismiss Plaintiffs’ Second Amended Complaint, arguing (1) that the Second Amended Complaint was untimely; (2) that the Second Amended Complaint’s negligence claim is barred by express preemption and implied conflict preemption; (3) that the Second Amended Complaint fails to state a plausible parallel claim for negligence; and (4) that the Second Amended Complaint’s consortium claim is barred by the defects in the underlying negligence claim. (Doc. 36 at ¶¶ 1-4). In response, Plaintiffs (1) admit that they filed the Amended Complaint late, but aver that Defendant suffered no prejudice, (2) assert that Plaintiffs’

claims are not preempted, arguing that “Plaintiffs have set forth cognizable parallel claims for negligence based on applicable federal regulations”; and (3) deny that Plaintiffs’ loss of consortium claim is barred if the negligence claim survives the motion to dismiss. (Doc. 41).

A. Timeliness of the Second Amended Complaint

As an initial matter, the Court addresses Defendant’s timeliness argument. Defendant asserts that Plaintiffs’ Second Amended Complaint is untimely. (Doc. 37 at 1). This Court previously granted Defendant’s first motion to dismiss, but gave the Plaintiffs twenty-one (21) days leave to file an amended complaint to cure the defect in their original complaint. (*See* Doc. 33). Plaintiffs’ Amended Complaint was due on October 19, 2012. Plaintiffs filed an Amended Complaint (Doc. 34) on October 31, 2012, twelve (12) days past the deadline set forth in the Court’s Order. Thereafter, Plaintiffs filed a Second Amended Complaint (Doc. 35) on November 5, 2012, seventeen (17) days past the deadline set forth in the Court’s Order. However, despite the untimeliness of the Plaintiffs’ Amended Complaints, the Court finds that Defendant has suffered no prejudice.

B. Negligence (Count I)

In Count I of their Second Amended Complaint, Plaintiffs assert a negligence claim against Defendant. (*See* Doc. 35 at ¶¶ 18-19). Defendant has moved to dismiss Plaintiffs’ negligence claim, arguing “the Second Amended Complaint suffers from the same defects as the original,” namely that the negligence claim is expressly preempted by the Medical Device Amendments (“MDA”) to the Food, Drug and Cosmetic Act. (Doc. 37 at 1, 3). Defendant further asserts that the Second Amended Complaint fails to state a plausible parallel claim for negligence. (Doc. 37 at 2).

This Court has previously addressed the issue of preemption and a parallel claim in its Memorandum and Order (Doc. 33) dismissing Plaintiffs' original Complaint. The MDA establishes a regime of premarket approval for new devices classified by the FDA as Class III devices.⁴ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008). Premarket approval is a rigorous process. *Id.* Manufacturers of Class III devices must submit what is typically a multi-volume application that includes, among other information, extensive reports of medical and clinical data and the device's proposed labeling. *Id.*; *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 304 (E.D. Pa. 2009). The FDA then spends an average of 1,200 hours reviewing each application, during which time the FDA may refer the application to a panel of outside experts or request additional data from the manufacturer. *Riegel*, 552 U.S. at 317-18 (citing § 360e(c)(1)(G); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996); 21 C.F.R. § 814.44(a)(2007)). Once a device receives premarket approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing § 360e(d)(6)(A)(i)). A manufacturer must submit any such proposed changes to the FDA for approval. *Id.* (citing § 360e(d)(6); 21 CFR § 814.39(c)). Devices approved pursuant to the PMA process are also subject to reporting requirements. *Id.* (citing § 360i). Even after a device receives premarket approval, the FDA may, and under some circumstances, must, revoke

⁴ Class III medical devices are devices which cannot be classified as Class I or Class II devices and are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . [present] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C). Only Class III devices are subject to premarket approval. *See id.* While Plaintiffs do not specifically plead that the device at issue here is a Class III device, Plaintiffs aver that the device was approved by the FDA pursuant to the premarket approval process. (*See* Doc. 35 at ¶¶ 6-9).

premarket approval based on data or information received from such reports or otherwise made known to the FDA. *Id.* at 319-20.

The MDA contains an express preemption provision. *See* § 360k(a); *Riegel*, 552 U.S. at 321. The provision states:

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a). Thus, a state law claim is preempted by the MDA if (1) the Federal Government has established requirements applicable to the device at issue, and (2) Plaintiffs' "common-law claims are based upon [state] . . . requirements with respect to the device that are 'different from or in addition to,' the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321-22. Premarket approval imposes "requirements" under the MDA. *Riegel* 552 U.S. at 322-23.

Plaintiffs aver that the device at issue in this case is a "medical device" as classified by the FDA. (Doc. 35 at ¶ 6). Plaintiffs further aver that FDA approved the device through the premarket approval process ("PMA"), and the device is subject to post-approval reporting requirements. (Doc. 35 at ¶ 7). Thus, the implant device at issue is subject to various requirements established by the federal government through the PMA process. Therefore, the first prong of the test for express preemption is satisfied. Also, like the claims in *Riegel*, safety and effectiveness are the very subjects of Plaintiffs' negligence claim. *See Riegel v. Medtronic*,

Inc., 552 U.S. 312, 323 (2008). Therefore, Plaintiffs' claim in Count I is preempted, if it is based on state requirements that are "different from or in addition to" the federal requirements established by the FDA through the MDA § 360k(a). *See Riegel*, 552 U.S. at 323.

In *Riegel*, the Supreme Court held that common-law duties are state "requirements." *Riegel*, 552 U.S. at 323-24. When success on state law claims would require Plaintiffs to show that the device "was unsafe or ineffective despite the PMA process," such claims "interfer[e] with the requirements already established by the MDA," and are thus preempted. *Williams v. Cyberonics, Inc.*, 388 Fed. Appx. 169, 171 (3d Cir. 2010); *see also Riegel*, 552 U.S. at 325 (state law that requires a manufacturer's device "to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme").

However, the preemption provision of the MDA bars claims premised on state common-law requirements only to the extent that the claims rely on common-law duties that *differ from or add to* FDA requirements. *See* § 360k(a); *Riegel*, 552 U.S. at 330. Section 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations[.]" *Id.* In such a case, "the state duties . . . 'parallel,' rather than add to, federal requirements." *Id.* Therefore, Plaintiffs' claim can survive if Plaintiffs allege that Defendant violated federal law in a way that parallels a state duty. *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 483 (W.D. Pa. 2012). Here, such a claim would amount to an allegation that the medical device did not adhere to the FDA-approved standards or regulations. *See Riegel*, 552 U.S. at 330; *Gross*, 858 F. Supp. 2d at 480-83; *Cyberonics*, 654 F. Supp. 2d at 306-07.

However, Plaintiffs fail to assert such a parallel claim. To adequately plead a parallel claim, "Plaintiffs cannot simply incant the magic words '[Defendant] violated FDA regulations'

in order to avoid preemption.” *Id.*; *Gross*, 858 F.Supp. 2d at 483 (quoting *In re Medtronic Inc.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)). “To properly allege parallel claims, the complaint must set forth facts showing ‘action or inaction in [defendants’] efforts to take part in the PMA process or implement its results.’” *Id.* (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008)).

As in the original Complaint, Plaintiffs have again failed to set forth any facts showing action or inaction in Defendant’s efforts to take part in the PMA process. While Plaintiffs have amended their Complaint to include citation to several provisions of the Code of Federal Regulations (“CFR”) (*see* Doc. 35 at ¶ 19)⁵ to support their claim that Defendant violated applicable laws, codes, and regulations, Plaintiffs have nevertheless failed to specify how the Defendant has violated those provisions. Instead, Plaintiffs merely list the CFR provisions and assert that Defendant was negligent in violating the listed provisions “as the metal shaft of the device at issue shattered into two pieces during normal and expected use.” (Doc. 35 at ¶ 19(i)-(x)). Accordingly, as before, Plaintiffs’ averment merely amounts to an incantation that “Defendant violated FDA regulations,” which is insufficient to avoid preemption. *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 483 (W.D. Pa. 2012) (finding the plaintiff’s references to federal regulations in his negligence claim were too vague and general to establish what standard of care the defendant allegedly breached). Therefore, the Court finds that Plaintiffs again fail to assert a parallel claim and that Plaintiffs’ negligence claim is preempted and should be dismissed for failure to state a claim.

⁵ Plaintiffs allege defendant was negligent in violating the following Code of Federal Regulations: 21 CFR §§ 820.70(a) *et seq.*, 21 CFR § 820.70(a)(2), 21 CFR § 820.70(a)(5), 21 CFR § 820.7(h), 21 CFR § 820.22, 21 CFR § 820.30, 21 CFR § 820.75, 21 CFR § 820.80 *et seq.*, and 21 CFR § 820.100. (*See* Doc. 35 at ¶ 19(i)-(x)).

Plaintiffs rely on *In re Medtronic*, noting in their brief that a negligence claim will survive preemption if the claim “adequately pleads that a specific device was not manufactured in accordance with its PMA specifications and the claim is brought under a state statute ‘providing a remedy for a violation of the FDCA.’” (See Doc. 40 at 4, quoting *In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009) (“[A]n adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications can survive preemption.”)). While Plaintiffs’ assertion might be a correct statement of the law, Plaintiffs have failed to adequately plead a negligence claim. Indeed, Plaintiffs’ Second Amended Complaint suffers the same defect as the complaint in *In re Medtronic*.

The plaintiffs in *In re Medtronic* averred in their complaint that the medical device was defective because the manufacturer “did not comply with the FDA’s Current Good Manufacturing Practices (‘CGMOs’) and Quality System Regulation (‘QSR’).” *In re Medtronic*, 592 F. Supp. 2d at 1157. The court noted that the plaintiffs claimed “that they are seeking only to enforce FDA requirements (the CGMPs/QSR) and, as a result, their manufacturing-defect claims are merely ‘parallel.’” *Id.* This is precisely the argument that Plaintiffs make in the instant case. (See Doc. 40 at 4-5).

The Plaintiffs’ claim in the instant case must be dismissed for the same reasons as the plaintiffs’ claims in *In re Medtronic*. There, the court concluded

Plaintiffs’ reliance on the CGMPs and QSR . . . does not save [Plaintiffs’] claims from preemption . . . [because] they are simply too generic, standing alone, to serve as the basis for Plaintiffs’ manufacturing-defect claims. . . . The FDA recognizes that the CGMPs and QSR simply cannot cover, in detail, all of the design, production, and marketing elements for every medical device in existence.

. . . Rather, they are intended to serve only as ‘an umbrella quality system,’ providing ‘general objectives’ medical-device manufacturers must seek to achieve.

In re Medtronic, 592 F. Supp. 2d at 1158. The court explained that because the plaintiffs failed to identify any specific requirements that were purportedly violated by the defendant, the plaintiffs sought to impose requirements that differed from the CGMPs and QSR, and thus their claims were insufficient to withstand a motion to dismiss. *In re Medtronic*, 592 F. Supp. 2d at 1158 (“Plaintiffs’ failure to allege in detail the federal requirement(s) purportedly violated by Medtronic also raises the specter of *Twombly*. Plaintiffs cannot simply incant the magic words ‘Medtronic violated FDA regulations’ in order to avoid preemption.”).

The court’s analysis in *In re Medtronic* is consistent with that in similar cases in the Western District of Pennsylvania. *See, e.g., Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 495 (W.D. Pa. 2012) (“Allowing a plaintiff to plead non-specific regulations as a basis for a parallel claim is inconsistent with the Supreme Court’s reasoning in *Riegel*, as well as the pleading requirements articulated in *Twombly*, *Iqbal*, and *Fowler*.”).

Here, as in *Gross*, “[t]his Court requires a greater level of specificity in pleading a parallel claim, rather than allowing claims premised on violations of general regulations to go forward merely because plaintiffs will supplement their pleadings at trial.” *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 495-96 (W.D. Pa. 2012). This Court dismissed Plaintiffs original Complaint, but granted Plaintiffs leave to amend and provided guidance on withstanding additional Rule 12(b)(6) motions. (*See Doc. 33 at 11*). Nevertheless, Plaintiffs have simply made vague references to general FDA manufacturing requirements without alleging facts concerning any specific requirements that Defendant DePuy Orthopedics purportedly violated.

See Riegel, 552 U.S. 312; *Gross*, 858 F. Supp. 2d at 495-96; *In re Medtronic*, 592 F. Supp. 2d at 1155-63.

The Court previously dismissed Plaintiffs' negligence claim as preempted by federal law (Doc. 33), but granted Plaintiffs an opportunity to amend their Complaint. *See Phillips v. County of Allegheny*, 515 F.3d 224, 245 (3d Cir. 2008) ("[I]f a complaint is subject to a Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile."). Because Plaintiffs have twice failed to plead their claims with sufficient specificity in a manner that parallels federal law, permitting further amendment would be futile.

C. Loss of Consortium (Count II)

Plaintiffs also assert a loss of consortium claim (Count II) that is derivative of Plaintiffs' negligence claim. Because the Court dismisses the negligence claim, the Court likewise dismisses the consortium claim, as it is derivative of the underlying negligence claim. *See, e.g., O'Connor v. Sandy Lane Hotel Co., Ltd.*, 496 F.3d 312, 318 (3d Cir. 2007); *Gorman v. Kohl's Dep't Stores, Inc.*, 2011 WL 4574514 (W.D. Pa. Sept. 30, 2011); *Scattaregia v. Shin Shen Wu*, 495 A.2d 552, 553 (Pa. Super. 1985); *Boarts v. McCord*, 511 A.2d 204, 209 (Pa. Super. 1986).

VI. CONCLUSION

For the reasons explained above, the Plaintiffs' Second Amended Complaint (Doc. 35) fails to satisfy the requirements of Rule 12(b)(6). Furthermore, because the Court previously granted the Plaintiffs leave to correct the deficiencies of their first Complaint (*See* Doc. 33), the Court finds that any further amendment would be futile. Accordingly, the Court will **GRANT**

Defendant's motion and will **DISMISS** Plaintiffs' Amended Complaint with prejudice. An appropriate order follows.

KIM R. GIBSON,
UNITED STATES DISTRICT JUDGE